Claims

1. The use of triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient of an aid to waking refreshed after sleeping.

2. The use of triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient for the preparation of a composition for enabling an individual to wake refreshed after sleeping.

3. The use of triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient for the preparation of a medicament for enabling an individual to wake refreshed after sleeping.

4. The use of triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, for the preparation of a sleep aid which also enables an individual to wake refreshed after sleeping.

5. The use of triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient of a sleep aid which also enables an individual to wake refreshed after sleeping.

6. The use of triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient for the preparation of a medicament for the treatment or

prevention of a sleep disorder which also enables an individual to wake refreshed after sleeping.

7. Use of triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient in the manufacture of a composition for the treatment of sleep disorders.

8. The use of triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient in the manufacture of a composition for inducing, prolonging and/or enhancing sleep and/or sleep quality.

9. A method for the treatment or prevention of grogginess, drowsiness or lethargy on waking from sleep in a mammal comprising the administration to the mammal in need thereof of a non-toxic effective dose of triprolidine or a salt or hydrate thereof in combination with at least one further active pharmaceutical agent prior to the desired sleeping time.

10. A method for enabling an individual to wake refreshed after sleeping comprising the administration to the individual in need thereof and prior to the desired sleeping time of a non-toxic effective dose of triprolidine or a salt or hydrate thereof in combination with at least one further active pharmaceutical agent.

11. A method for aiding an individual's sleep and for also enabling the individual to subsequently wake refreshed after sleeping comprising the administration to the individual in need thereof and prior to the desired sleeping time of a non-toxic effective dose of triprolidine or a salt or hydrate thereof in

combination with at least one further active pharmaceutical agent.

12. A method of treating sleep of a person suffering from a sleep disorder, which method comprises administration of an effective dose of triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient to such a person.

13. A method for inducing, prolonging and/or enhancing sleep, which method comprises administration of an effective dose of triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient to a person desirous of achieving sleep.

14. A waking refreshed aid comprising triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient in association with a pharmaceutically acceptable carrier therefor and instructions for administration thereof at or just before the desired sleeping time.

15. A pharmaceutical formulation for the treatment or prevention of grogginess, drowsiness or lethargy on waking after sleeping, comprising triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient in association with a pharmaceutically acceptable carrier therefor and instructions for administration thereof at or just before the desired sleeping time.

16. A pharmaceutical formulation for enabling an individual to wake more refreshed after sleeping,

comprising triprolidine or a salt or hydrate thereof, in combination with at least one further active pharmaceutical agent, as active ingredient in association with a pharmaceutically acceptable carrier therefor and instructions for administration thereof at or just before the desired sleeping time.

17. The use of triprolidine or a salt or hydrate thereof as claimed in any of claims 1 - 8, wherein the said at least one further active pharmaceutical agent is intended to be used in the treatment of a condition having sleep disorder as a symptom or potential symptom.

18. The use of triprolidine or a salt or hydrate thereof as claimed in any of claims 1 - 8 or 17, wherein the said at least one further active pharmaceutical agent is selected from: an active agent used in the treatment of pain relief, migraines, allergies, colds, flu, coughs or anxiety; an active agent used as an anaesthetic, antiviral agent, antidepressive agent, decongestant or disinfectant; or an active agent used in women's health

19. The use of triprolidine or a salt or hydrate thereof as claimed in any of claims 1 - 8 or 17-18, wherein the said at least one further active agent is independently selected from any one or more of the following agents or their active salts or hydrates: Ibuprofen, Fluribiprofen, Ketoprofen, Aspirin, Paracetamol, Aceclofenac, Codeine, Naproxen, Indomethacin, Diclofenac, Cox II, Meloxicam, Nitric oxide, Caffeine, Acrivastine, Cetirizine, Loratadine, Fexofenadine, Terfenadine, Beclomethasone, Hydrocortisone, Triptan, Almotriptan, Rizatriptan, Naratriptan, Sumatriptan, Zolmatriptan, Domperidone, Acetylcysteine, Menthol, Ambroxol, Carbocisteine, Dextromethorphan,

Guaiphenesin, Ipecacuanha, Phenylpropanolamine, Liquorice, Marshmallow, Squill, Honey, Glycerine, Aniseed, Benzocaine, Lidocaine, Amantadine, Aciclovir, Famciclovir, Ganciclovir, Rimantadine, Penciclovir, Tribavirin, Valaciclovir, Neuraminidase inhibitors, Zanamir, Oseltamir, Benzalkonium chloride, Cetylpyridinium chloride, Dichlorobenzyl alcohol, Amylmetacresol, Dequalinium chloride, Hexylresorcinol, Eucalyptus oil, Thymol, Calamine, Propranalol, Chamomile, Hops, Passion flower, Valarian, Melatonin, Eucalyptus, Phenylepherine, Pseudoephedrine, Cranberry and Bisphosphonates.

20. The use of triprolidine as a salt or hydration thereof as claimed in any of claim 19, wherein the said active pharmaceutical agent is independently selected from any one or more of the following agents or their active salts or hydrates Ibuprofen, Fluribiprofen, Cox II such as meloxicam, triptans, Domperidone, Ambroxol, Dextromethorphan, Guaiphenesin, Lidocaine, Amantadine, Hexylresorcinol, dcba, amc, Propranalol, pseudoephedrine and Bisphosphonates or a pharmaceutically acceptable salt of any of the foregoing.

21. The use of triprolidine or a salt or hydrate thereof as claimed in any of claims 1 - 8 or 17-20, wherein the further active pharmaceutical agent may be combined with triprolidine in a single dosage form or in a pharmaceutical pack containing at least two dose forms, one being triprolidine and the other being the said further active pharmaceutical agent.

22. The use of triprolidine or a salt or hydrate thereof as claimed in any of claims 1 - 8 or 17-21, wherein the said pack includes instructions on how to take the

combination of triprolidine with the said further agent.

23. The use of triprolidine or a salt or hydrate thereof as claimed in any of claims 1 - 8 or 17-22, wherein the dosage of the said further pharmaceutically active agent is one suitable for the treatment selected.

24. The use as claimed in any of claims 1-8 or 17-23, wherein the dose of triprolidine administered to the user prior to sleeptime is between 0.01mg and 20mg.

25. The use as claimed in any of claims 1-8 or 17-24, wherein the dose of triprolidine administered to the user before sleeptime is up to 20mg.

26. The use as claimed in any of claims 1-8 or 17-25, wherein the said further active pharmaceutical agent may include, without limitation, antacids, analgesics, anti-inflammatories, antibiotics, laxatives, anorexics, antiasthmatics, antidiuretics, antiflatulents, antimigraine agents, antispasmodics, additional sedatives, antihyperactives, tranquilizers, antihistamines, decongestants, betablockers, antidepressives, hormones and combinations thereof.

27. The use as claimed in any of claims 1-8 or 17-26, wherein the said dosage forms may be combined into a combined dosage form for simultaneous administration.

28. The method as claimed in any of claims 9-13, wherein the dose of active ingredient of triprolidine administered is between 0.01 and 20mg.

29. The method as claimed in any of claims 9-13 wherein the dose of active ingredient of triprolidine administered is up to 20mg.

30. The pharmaceutical formulation as claimed in any of claims 15 or 16, wherein the instructions for administration instruct a single dose comprising active ingredient of triprolidine of up to 20mg prior to sleeptime.

31. The pharmaceutical formulation as claimed in any of claims 15 or 16, wherein the instructions for administration instruct a single dose comprising active ingredient of triprolidine of between 0.01 and 20mg prior to sleeptime.

32. A waking refreshed aid as claimed in claim 14, wherein the instructions for administration instruct a single dose of the triprolidine active ingredient of up to 20mg prior to sleeptime.

33. A waking refreshed aid as claimed in claim 14, wherein the instructions for administration instruct a single dose comprising the active ingredient triprolidine of between 0.01 and 20mg prior to sleeptime.

34. A method as claimed in any of claims 9-13, 28 or 29, wherein the triprolidine is in the form of triprolidine hydrochloride.

35. A method as claimed in any of claims 9-13, 28, 29 or 34, wherein the person is suffering from a sleep disorder.

36. A method as claimed in any of claims 9-13, 28, 29 or 34, wherein the person is not suffering from a sleep disorder but is desirous of achieving a feeling of waking refreshed upon waking.

37. A method as claimed in any of claims 9-13, 28, 29 or 34-36, wherein the active ingredients are administered orally, nasally, optically, rectally, pulmonarily, transdermally or sub-lingually.

38. A method as claimed in claim 9-13, 28, 29 or 34-37, wherein the active ingredients are administered in the form of a tablet, capsule, drink, lozenge, drops, emulsion, dry powder, suspension, pastille, patch, suppository, syrup, consumable film such as a buccal wafer, sub-lingual spray or nasal spray.

39. A method as claimed in any one of claims 9-13, 28, 29, 34-38, wherein the active ingredients are administered to the mucous membranes of the nasal cavity.

40. A method as claimed in any of Claims 9-13, 28, 29 or 34-39, wherein the active ingredients are administered as a solution or suspension spray or as a powder.

41. A method as claimed in any of claims 9-13, 19, 20 or 25-31 in which the active ingredients are administered between 1 minute and 2 hours prior to sleeptime.

42. Use as claimed in any of claims 1-8 or 17-25, wherein the triprolidine is in the form of triprolidine hydrochloride.

43. Use as claimed in any one of Claims 1-8, 17-25 or 42, wherein the composition is for oral administration.

44. Use as claimed in any of claims 1-8, 17-25, 42 or 43, wherein the composition is in the form of a tablet, capsule, drink, lozenge, drops, emulsion, dry powder, suspension, pastille, patch, suppository, syrup, consumable film such as a buccal wafer, sub-lingual spray or nasal spray.

45. Use as claimed in any one of Claims 1-8, 17-25 or 42, wherein the composition is for administration to the mucous membranes of the nasal cavity.

46. Use as claimed in any of Claims 1-8, 17-25 or 42, 43 or 45, wherein the composition is a solution or suspension or a powder.

47. The use as claimed in any of claims 1-8, 17-25, or 42-46, wherein the triprolidine forms the active ingredient of a formulation which contains a blend of two or more diluents, one of which may also serve as a disintegrant.

48. The use as claimed in any of claims 1-8, 17-25, 42, 43, 45 or 47, wherein the triprolidine forms the active ingredient of a formulation, which comprises a saccharide diluent.

49. The use as claimed in claim 48, wherein the triprolidine formulation further comprises a disintegrant.

50. The use as claimed in claim 49, wherein the triprolidine formulation further comprises the saccharide diluent and the disintegrant in the ratio of 1-10 parts by weight saccharide diluent to 1 part by weight of disintegrant.

51. The use as claimed in claim 49 or Claim 50, wherein the saccharide diluent is lactose, and the disintegrant is croscarmellose sodium.

52. The use as claimed in any one of Claims 47 to 51, wherein the triprolidine formulation further comprises a lubricant.

53. The use as claimed in claim 52, wherein the lubricant is magnesium stearate.

54. The use as claimed in any one of Claims 47 to 53, wherein the triprolidine formulation is formed with a coating of a hydrophilic polymer.

55. The use as claimed in claim 54, wherein the hydrophilic polymer is a methylated cellulose derivative.

56. The use as claimed in any one of Claims 47 to 55, which is free of ingredients intended or effective to sustain or prolong release of the active ingredients.

57. The use as claimed in any of claims 1-8, 17-25 or 42-56, wherein the dosage of the said further pharmaceutically active agent is one suitable for the treatment selected.

58. The use as claimed in any of claims 1-8, 17-25 or 42-57, wherein a single dosage form of said pharmaceutically active agent is in the range 0.1mg - 2000mg.

59. A method of manufacturing a formulation as claimed in any one of Claims 45 to 58, which involves direct compression of the ingredients into a tablet without an intermediate granulation stage.

60. The uses of triprolidine, in combination with a further active pharmaceutical agent, as hereinbefore described and with reference to the examples.

61. The methods for the treatment of grogginess as hereinbefore described and with reference to the examples.

62. The tablets as hereinbefore described and with reference to the examples.

63. The pharmaceutical formulations as hereinbefore described and with reference to the examples.

64. The waking refreshed aids as hereinbefore described and with reference to the examples.

65. The method for enabling an individual to wake refreshed after sleeping as hereinbefore described and with reference to the examples.

66. A waking refreshed aid as hereinbefore described and with reference to the examples.

67. A pharmaceutical formulation as hereinbefore described and with reference to the examples.

68. Use of triprolidine, in combination with at least one further active pharmaceutical agent, as active ingredient in the manufacture of a composition for the treatment of sleep disorders as hereinbefore described and with reference to the examples.

69. The use of triprolidine, in combination with at least one further active pharmaceutical agent, as active ingredient in the manufacture of a composition for inducing, prolonging and/or enhancing sleep as hereinbefore described and with reference to the examples.

70. A method of treating sleep of a person suffering from a sleep disorder, which method comprises administration of an effective dose of triprolidine, in combination with at least one further active pharmaceutical agent, as active ingredient to such a person as hereinbefore described and with reference to the examples.

71. A method for inducing, prolonging and/or enhancing sleep, which method comprises administration of an effective dose of triprolidine, in combination with at least one further active pharmaceutical agent, as active ingredient to a person desirous of achieving sleep as hereinbefore described and with reference to the examples.